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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,938	04/12/2004	Chin Ying Hsiao	09395.0001-00000	4416

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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER

MAYER, SUZANNE MARIE

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 11/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/822,938

Applicant(s)

HSIAO ET AL.

Examiner

Suzanne M. Mayer, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8-3-2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54-76 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 54-76 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8-16-2005</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. The amendments filed under 35 U.S.C. 111(a) are acknowledged. Applicant's have cancelled claims 1-53. Claims 54-76 have been added and are pending and under examination.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on August 16, 2005 has been considered by the examiner. See signed and attached PTO-1449.

Withdrawal of Rejections and Objections

3. Any rejections and/or objections cited in the previous Office action and not expressly reiterated below are hereby withdrawn.

Response to Arguments

4. Applicant's arguments of rejections under 35 U.S.C. 102(b) and 103(a), see p.14-19, filed August 3, 2005, with respect to claims 1-17 and 1-40, respectively, have been fully considered and are persuasive in view of the amended claims for the 102(b) rejection, and in view of the arguments presented by Applicants in regard to the 103(a) rejection. The rejections have been withdrawn.

New Rejections/Objections

Claim Objections

5. Claim 61 is objected to because of the following informalities: In the first instance that an acronym appears, it should be spelled out followed by the acronym in parenthesis. Appropriate correction is required.

Claim Rejections - 35 USC § 112-2nd Paragraph

6. Claim 60 recites the limitation "wherein the low temperatures is at about 4 °C" in reference to the method of claim 54. There is insufficient antecedent basis for this limitation in the claim because no reference to any temperature is recited in claim 54.

7. Claim 54 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what "a time sufficient to permit the production of a collagen composition" actually is. A "time sufficient" is an extremely subjective limitation that, for example, can be interpreted to mean from 1 minute to 10 years.

Claim Rejections - 35 USC § 112-1st Paragraph

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 54-63 and 65-67 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of producing collagen

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monomers by fermenting collagen contain tissues with microorganisms from the genus *Bacillus*, *Lactobacillus* or *Pseudomonas*, does not reasonably provide enablement for the use of every single kind of microorganism in existence. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized in *re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The court in *Wands* states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In the instant case, undue experimentation would be expected because a skilled artisan would be required to ascertain and work out exactly what kinds of

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microorganisms work with the claimed invention. The specification simply sites that those which are Gram positive and are generally regarded as safe (GRAS) will work. However, a skilled artisan clearly recognizes that when a microorganism is fermented, it is the constitution/genetic make-up of the microorganism will determine what the predominant proteins, enzymes, compounds and bi-products that are produced into the culture and medium which perform the duties of breaking down the collagen tissue into the correct monomeric alpha-form. Thus each and every different microorganism will produce their own bi-products that may or may not work in the claimed invention, but the only way a skilled artisan would be able to ascertain this is with under experimentation which would be an extensive amount. The directions and guidance in the specification is drawn exclusively to the genus *Bacillus* and no other examples or explanations exist. The relative skill in the art is exceptionally high and a skilled artisan would clearly recognize that those microorganisms found within the genus of *Bacillus* and perhaps *Aspergillus* as cited in the prior art might be adaptable to the present claimed invention, however, the only way to ascertain if anyothers worked as well would be to experiment unduely. The art is very unpredictable (as anyone who has had a bad glass of beer or wine can tell you that fermentation is an unpredictable art at the best of times) and finally the breadth of the claims are outside the scope of what the specification clearly supports.

10. Claim 54-76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to

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which it pertains, or with which it is most nearly connected, to make and/or use the invention. The factors to be considered in determining whether undue experimentation is required are stated above.

The claims are drawn to a method of producing collagen monomers of the α -form (that is approximately 100 kDa when assessed by SDS-PAGE) by adding collagen-containing tissues with most any kind of microorganism and fermenting said tissues. This, according to the claims, produces the alpha-form of collagen (see claims 54 and 68, steps (c)). However, as a skilled artisan is well aware, collagen is comprised of three forms/components that make-up collagen, a monomeric α form, a polymeric β and also a γ form, each of which have distinguishing molecular weights. Applicant's have disclosed as much in their specification as well as in their information disclosure statements. However, an essential missing element and step in the method and process is how a skilled artisan obtains only the α -form. It is wholly unclear in the claims and in the specification, how this result is even achieved. In the Independent claims, 54 and 67, it is claimed that the method requires "allowing the microorganisms to ferment the collagen-containing tissues for a time sufficient to permit the production of a collagen composition weighing at least about 10%-40% of the weight of the collagen-containing tissues, wherein the collagen composition comprises mostly collagen monomers....."; however, it is not disclosed in this claim or any of the dependent claims or in the specification how the other forms/components of collagen gets separated from the α -form. Thus a skilled artisan would be required to figure this out on their own, because the step of extracting the α form from the β form is not

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disclosed whatsoever in the specification. Furthermore, Applicant's own examples add to this confusion because some obtain only the α form (Examples 4 and 5), whereas others obtain the α and β forms (Examples 2 and 3); this is further complicated by the fact that the protocols in the Examples follow relatively the same steps. The state of the prior art is such nowhere is it described how simply fermenting collagen will ultimately give rise to one particular form/component of collagen (e.g. α or β) over another form/component; the relative skill of those in the art and they would recognize that the predictability of the art suggests that simply fermenting collagen with microorganisms is not going to single handedly produce one form/component over the other, and there will necessarily need to be at the minimum *at least* one additional step of some sort, however, what that step(s) is and where it might occur in the process is never mentioned or suggested anywhere in the specification or claims.

When the factors are considered in their entirety, the Wands analysis dictates a finding of undue experimentation and thus, the claims are not enabled.

Conclusion

11. No claim is allowed.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne M. Mayer, Ph.D. whose telephone number is 571-272-2924. The examiner can normally be reached on Monday to Friday, 7.30am to 4.00pm.

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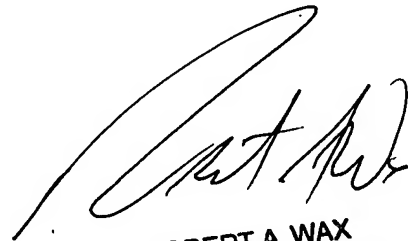
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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31 October 2005



ROBERT A. WAX
PRIMARY EXAMINER